

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)

Sheet 1 of 6

Complete if Known

Application Number	10/597,688
Filing Date	August 3, 2006
First Named Inventor	Jeffrey RUBERTI
Art Unit	2627
Examiner Name	Not Yet Assigned
Attorney Docket Number	20780-025

U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No. ¹	Document Number	Publication Date Mm-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code ² (If known)		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A1	3,875,302		04/01/1975	Inoue
A2	4,472,542		09/18/1984	Nambu
A3	4,663,358		05/05/1987	Hyon
A4	4,772,287		09/20/1988	Ray
A5	4,904,260		02/27/1990	Stoy
A6	5,047,055		09/10/1991	Bao
A7	5,071,437		12/10/1991	Steffee
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A11	5,705,296		01/06/1998	Kamauchi
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A17	6,268,405		07/31/2001	Yao

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date Mm-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁴
		Country Code/Number ⁴ Kind Code ⁵ (If known)				
B1	WO 01/12107 A1		02/22/2001	LAMBRECHT	English	
B2	WO 02/054978 A2		07/18/2002	LAMBRECHT	English	
B3	JP 04 338326A		11/25/1992	OKAMURA	W/English Translation	
B4	JP 03215417A		09/20/1991	YAMAUCHI et al.	W/English Translation	
B5	EP 1229873		08/14/2002	MARCOLONGO	English	

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NON PATENT LITERATURE DOCUMENTS					
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	C1	AAOS, Musculoskeletal Conditions in the U.S., Feb. 1992-1988, 1992, AAOS			
	C2	Bao, Q.B., & Yuan, H. A., "Nucleus Replacement," Spine, Vol. 27, No. 11, 2002, 1245-1247			
	C3	Bao, Q. & Yuan, H.A. "Prosthetic Disc Replacement: The Future?," Clinical Orthopaedics and Related Research, No. 394, pp 139-145, 2002			
	C4	Zeegers, W. S., et al, "Artificial disc replacement with the modular type SB Charit III: 2-year results in 50 prospectively studied patients, Eur Spine J, 8:210-217, 1999			
	C5	Wiesel, S.W. et al, "Industrial Low-Back Pain-A Prospective Evaluation of a Standardized Diagnositc and Treatment Protocol," SPINE, Vol. 9, No. 2, 199-203, 1984			
	C6	Vago, R., "Novel Natural Materials for Bone Substitutes and Hard Tissue Remodeling," http://www.bgu.ac.il/bgn/bone.html			
	C7	Bao, Q. et al, "The artificial disc: theory, design and materials," Biomaterials Vol. 17, No. 12, (1996) 1157-1167			
	C8	Urushizaki, F. et al, "Swelling and mechanical properties of poly(vinyl alcohol) hydrogels," International Journal of Pharmaceutics, 58 135-142, 1990			
	C9	UPMC Surgeons Implanting Metal Cages into the Spine to Treat Chronic Low Back Pain, Neurosurgery News, 1999, University of Pittsburgh			
	C10	Takeshita, H. et al, "Gelation Process and Phase Separation of PVA Solutions as Studied by a Light Scattering Technique," Macromolecules 32, 7815-7819, 1999			
	C11	Oka, M. et al, "Development of artificial articular cartilage," Proc Instn Mech Engrs Vol. 214 Part H, 59-68, 2000			
	C12	Onuki, A. & Puri, S., "Spinodal decomposition in gels," Physical Review E, Vol. 59, No. 2, Feb. 1999, R1331-R1334			
	C13	Mike, C., "FDA Approves Bone Graft," 2002, http://www.news.wisc.edu/view.html?get=7640			
	C14	Takeshita, H. et al, "Small-angle neutron scattering studies on network structure of transparent and opaque PVA gels," Physica B 311 (2002) 78-83			
	C15	Lozinsky, V. I. et al, "Swelling behavior of poly(vinyl alcohol) cryogels employed as matrices for cell immobilization," Enzyme Microb. Technol, Vol. 18, 561-569, 1996			
	C16	Juarez, K.K. & An, H.S., "Artificial Disc Replacement," Spineuniverse.com			

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	C17	Kawanishi K. et al, "Thermodynamic consideration of the sol-gel transition in polymer solutions," 35 th Annual Meeting of the Society of Polymer Science, Japan, 1986				
	C18	"New Implants Offer Relief of Spine 2001, Medical Device and Diagnostic Industry				
	C19	Takeshita, H., et al, "Spinodal Decomposition and Syneresis of PVA Gel, Macromolecules 2001, 34, 7894-7898				
	C20	Diwan, A. D. et al, "Current Concepts in Intervertebral Disk Restoration," Tissue Engineering in Orthopedic Surgery, Vol. 31, No. 3, pp 453-464, July 2000				
	C21	Peppas, N. A. et al, "Physicochemical Foundations and Structural Design of Hydrogels in Medicine and Biology," Annu. Rev. Biomed. Eng., 02-9-20, 2000				
	C22	Willcox, P. J., et al, "Microstructure of Poly(vinyl alcohol) Hydrogels Produced by Freeze/Thaw Cycling, Journal of Polymer Science: Part B: Polymer Physics, Vol. 37, 3438-3454 (1999)				
	C23	Bray, J.C. & Merrill, E. W., "Poly(vinyl alcohol) Hydrogels for Synthetic Articular Cartilage Material," Biomed. Mater. Res., Vol. 7, pp. 431-443 1973				
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	C27	Hong, P. et al, "Effects of Mixed Solvent on Gelation of Poly(vinyl alcohol) Solutions," Journal of Applied Polymer Science, Vol 79, Issue: 6, Date: 7 February 2001, Pages: 1113-1120				
	C28	Hassan C. M. & Peppas N. A., "Structure and Morphology of Freeze/Thawed PVA Hydrogels," Macromolecule, Vol. 33, No. 7, 2472-2479, 2000				
	C29	Griffith, S. L. et al, "A Multicenter Retrospective Study of the Clinical Results of the LINK® SB Charite Intervertebral Prosthesis," SPINE, Vol. 19, No. 16, 1842-1849, 1994				
	C30	Flory, P.J., "Principles of Polymer Chemistry, 1953, Ithaca and London: Cornell University Press				
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NON-PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	C32	Choi, J. H., et al, "Rheological Properties of Syndiotacticity-Rich Ultrahigh Molecular Weight Poly(vinyl alcohol) Dilute Solution," Journal of Applied Polymer Science, Vol. 82, 569-576 (2001)			
	C33	Doehring, T.C. et al, "Cyclic Load-Displacement Characteristics of Lumbar Functional Spinal Units, 46 th Annual Meeting, Orthopaedic Research Society, March 12-15, 2000			
	C34	Damshkain, L. G., et al, "Study of Cryostructuraron of Polymer Systems. XV. Freeze-Thaw-Induced Formation of Cryoprecipitate Matter from Low-Concentrated Aqueous Solutions of Poly(vinyl alcohol), Journal of Applied Polymer Science, Vol. 74, 1978-1986 (1999)			
	C35	Darwisi, D., et al, "Characterization of poly(vinyl alcohol) hydrogel for prosthetic intervertebral disc nucleus," Radiation Physics and Chemistry 63 (2002) 539-542			
	C36	Gomes, K. et al, "The Effect of Dehydration History on Associating Hydrogels for Nucleus Pulpous Replacement, Society for Biomaterials, 28 th Annual Meeting Transactions, 2002			
	C37	Hassan C., M. et al, "Diffusional characteristics of freeze/thawed poly(vinyl alcohol) hydrogels: Applications to protein controlled release from multilaminate devices," European Journal of Pharmaceutics and Biopharmaceutics 49 (2000) 161-165			
	C38	Elias, H.G., "Theta Solvents," Brandrup, J. and E. H. Immergut, Polymer Handbook 3rd Ed., John Wiley & Sons, NY 1989			
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	C40	Lozinsky, V. I., et al, "Study of Cryostructuraton of Polymer Systems, XIV. Poly(vinyl alcohol) Cryogels: Apparent Yield of the Freeze-Thaw-Induced Gelation of Concentrated Aqueous Solutions of the Polymer," Journal of Applied Polymer Science, Vol. 77, 1822-1831 (2000)			
	C41	Nakane, K., et al, "Properties and Structure of Poly(vinyl alcohol)/Silica Composites, Journal of Applied Polymer Science, Vol. 74, 133-138 (1999)			
	C42	Hassan, C., M. et al., "Modeling of crystal dissolution of poly(vinyl alcohol) gels produced by freezing/thawing process," Polymer 41 (2000) 6729-6739			

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	C43	Hickey, A. S. & Peppas N.A., "Solute diffusion in poly(vinyl alcohol)/poly(acrylic acid) composite membranes prepared by freezing/thawing techniques," Polymer, Vol. 38 No. 24 1997 5931-5936		
	C44	Li, J. K., et al, "Poly(vinyl alcohol) nanoparticles prepared by freezing-thawing process for protein/peptide drug delivery," Journal of Controlled Release 56 (1998) 117-126		
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	C47	Marolongo, M., et al, "Novel Hydrogel Copolymers for Intervertebral Disc Replacement," Sixth World Biomaterials Congress Transactions, 2000		
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	C49	Narasimhan, B. & Peppas, N.A., "Molecular Analysis of Drug Delivery Systems Controlled by Dissolution of the Polymer Carrier," Journal of Pharmaceutical Sciences, Vol. 86, No. 3, March 1997		
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	C53	Strawhecker, K.E. & Manias E., "AFM of Poly(vinyl alcohol) Crystals Next to an Inorganic Surface," Macromolecules, 2001, 34, 8475-8482		
	C54	Strawhecker, K.E. & Manias, E., "Structure and Properties of Poly(vinyl alcohol)INA+ Montmorillonite Nanocomposites," Chem. Mater, 2000, 12, 2943-2949		
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